SYSTEMS AND METHODS FOR ENABLING AN UNTRAINED OR NOVICE END-USER TO RAPIDLY BUILD CILINICAL TRIALS DATA MANAGEMENT SYSTEMS COMPLIANT WITH ALL APPROPRIATE REGULATORY GUIDANCES

ABSTRACT OF THE DISCLOSURE

Systems and methods for enabling an untrained or novice end-user to rapidly build clinical trials data management systems that are compliant with all appropriate regulatory guidelines are disclosed. An exemplary embodiment is a software package, executed by a computer, that contains a specified knowledge base of clinical trials regulations and provides an interactive venue through which information and specifications for a particular clinical trial is collected by the user. The knowledge base of clinical trials regulations and the user-provided information are combined by the software to produce a set of "creation rules" unique to the particular clinical trial. The creation rules are then utilized by the software to automatically generate a clinical trials database management system, that is customized specifically to the particular clinical trial and adheres to the appropriate regulations that must govern the particular clinical trial.

18